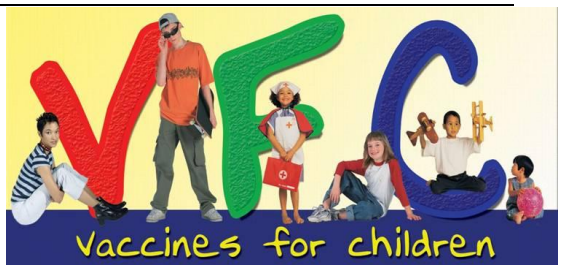
MONTANA
Department of Public Health & Human Services

Immunization Program



Vaccine Incident Report

Follow the procedures below when your publicly purchased vaccine has experienced out-of-range storage temperatures. Use a separate report for each affected storage appliance.

1. Do not use or discard the affected vaccine.
2. Contact your Vaccine Coordinator or Alternate Vaccine Coordinator (if primary is unavailable).
3. Isolate the affected vaccine, mark the boxes with an "X," and post a clear "Do Not Use" sign.
4. If the situation is temporary or quickly remedied (w/in 3 hours), keep the vaccine in its original storage unit with the door closed.
5. If necessary, move the vaccine to a working storage unit or your emergency storage location. Be sure to monitor temperatures at this location.
6. Contact the Montana Immunization Program 444-5580.
7. Record the following information about the incident:

Facility Name:_____**VFC #**_____

Reported by:_____**Telephone #**_____**Date Reported**_____

Storage Unit Involved:_____
(Use a separate report for each affected storage appliance.)

- When was the incident discovered? Date_____ Time_____am/pm (circle one)
- Room Temperature at time of discovery: _____C / F
- Temperature of storage unit at time of discovery: Refrigerator_____C / F Freezer_____C / F
  (Record temperature for refrigerator and freezer if a combined unit.)
- Last known temperature recording prior to incident: Date_____Time_____am/pm (circle one)
- Temperature at last known recording: Refrigerator_____C or F Freezer_____C or F
  (Record temperature for refrigerator and freezer if a combined unit.)
- Time interval vaccine was exposed to out-of-range temperatures:_____days _____hrs_____minutes
  (Estimate the worst case scenario based on last recorded temperatures. If using a data logger, use the graphing function to determine the exact interval.)
- Has the affected vaccine experienced previous temperature excursions? ____Yes ____No

8. Inventory the affected vaccine in columns 1–5 of the Vaccine Inventory Table on page 2 of this form.
9. Contact the manufacturer of the affected vaccine to determine its viability. Use the contact information on page 2. The manufacturer will need the information recorded above to determine vaccine viability. Record the information from the manufacturer in columns 6–8 of the Vaccine Inventory Table.

Vaccine Inventory Table (Copy this page if you need more rows in the table.)

Vaccine Name	Manufacturer	Lot #	Expiration Date	# of Doses	Disposition per Manufacturer (i.e., viable, wasted, exp date changed, etc.)	Call Ref# or Representative's Name	Date of Call

10. If the manufacturer determines the vaccine is viable: a) Mark the date of this report next to the "X" on the package. This indicates that the vaccine has experienced a temperature excursion and references this report; b) If the expiration date of the vaccine has changed, clearly indicate the new expiration date on the package; and c) Return the vaccine to your inventory. Do not return vaccine to a malfunctioning storage unit until it can reliably maintain vaccine storage temperatures.
11. If the manufacturer determines that the vaccine is wasted: a) Fill out a Wasted and Expired Vaccine Return Form and follow the instructions on the form for returning the vaccine to McKesson; b) Contact the Montana Immunization Program (444-5580) for a shipping label; c) Account for the vaccine on your Monthly Vaccine Report.
12. To finish this report, provide the following information: Briefly describe the incident:

    _____
    _____
    _____

    What steps will be taken to prevent this from happening in the future?

    _____
    _____
    _____

13. Once completed, Fax or mail this report to the Montana Immunization Program, PO Box 202951, 1400 Broadway, Helena, Montana 59620 , Fax 444-2920. This report serves as a record of the incident, the steps taken to determine vaccine viability, and the disposition of the affected vaccine. **Keep a copy for your records.**

Vaccine Manufacturer Contact Information

GlaxoSmithKline	919-305-3970	MedImmune	877-633-4411
Merck	800-637-2590	Novartis	800-244-7668
Sanofi Pasteur	800-822-2463	Wyeth	800-934-5556

MT Immunization Program use only.
Review initials/date_____
Corrective Action Required ___Yes ___No
Completed initials/date_____
Vaccine Manager sign-off_____
Entered in temp excursion database:_____